



DEPARTMENT OF HEALTH AND HUMAN SERVICES

245641  
Food and Drug Administration  
Seattle District  
Pacific Region  
22201 23rd Drive SE  
Bothell, WA 98021-4421

Telephone: 425-486-8788  
FAX: 425-483-4996

February 5, 2004

**VIA CERTIFIED MAIL  
RETURN RECEIPT REQUESTED**

In reply refer to Warning Letter SEA 04-20

Takao Saito, Owner  
Home Sushi Bar  
3720 Factoria Blvd SE  
Bellevue, Washington 98006

**WARNING LETTER**

Dear Mr. Saito:

On January 13 and 14, 2004, we inspected your firm, located at 3720 Factoria Blvd SE, Bellevue, Washington. We found that you have serious deviations from the seafood Hazard Analysis and Critical Control Points (HACCP) regulations, Title 21, Code of Federal Regulations, Part 123 (21 CFR 123). In accordance with 21 CFR 123.6(g), failure of a processor to have and implement a HACCP plan that complies with this section or to otherwise operate in accordance with the requirements of this part, renders the fishery products adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C 342 (a)(4). Accordingly your California rolls, Kapa/Teka Combo rolls, Odd Couple rolls, Spicy Tuna rolls, and Sushi Combo rolls are adulterated in that the products have been prepared, packed, or held under insanitary conditions whereby they may have become contaminated with filth, or whereby they may have been rendered injurious to health. You can find the Act, the Seafood HACCP regulations and the Fish and Fisheries Products Hazards & Controls Guidance, 3<sup>rd</sup> edition, June 2001 (the Hazard Guide), through links in FDA's homepage at [www.fda.gov](http://www.fda.gov).

The deviation is as follows:

**You must conduct a hazard analysis to determine whether there are food safety hazards that are reasonably likely to occur and you must have a written HACCP plan to control any food safety hazards that are reasonably likely to occur, to comply with 21 CFR 123.6(a), and (b). However, your firm does not have a HACCP plan to control the food safety hazard of pathogen growth and toxin production in your California rolls, Kappa/Teka Combo rolls, Odd Couple rolls, Spicy Tuna rolls, and Sushi Combo rolls. This deviation was previously brought to your attention in our letter of October 30, 2003.**

Takao Saito, Owner  
Home Sushi Bar, 3720 Factoria Blvd SE, Bellevue, Washington 98006  
Re: Warning Letter SEA 04-20  
Page 2

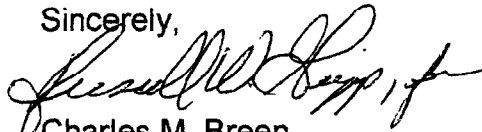
We may take further action if you do not promptly correct these violations. For instance, we may take further action to seize your product(s) and/or enjoin your firm from operating.

Please respond in writing within three (3) weeks from your receipt of this letter. Your response should outline the specific things you are doing to correct these deviations. You may wish to include in your response documentation such as your completed HACCP plan or other useful information that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, we expect that you will explain the reason for your delay and state when you will correct any remaining deviations.

This letter may not list all the deviations at your facility. You are responsible for ensuring that your processing plant operates in compliance with the Act, the Seafood HACCP regulations, and the Current Good Manufacturing Practice regulations (21 CFR Part 110). You also have a responsibility to use procedures to prevent further violations of the Act and all applicable regulations.

Please send your reply to the Food and Drug Administration, Attention: Michael J. Donovan, Compliance Officer, 22201 23<sup>rd</sup> Drive SE, Bothell, Washington 98021. If you have questions regarding any issue in this letter, please contact Mr. Donovan at (425) 483-4906.

Sincerely,



Charles M. Breen  
District Director

Enclosures:  
Form FDA 483

cc: WSDA with disclosure statement